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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,463	01/18/2002	Jeannette C. Roberts	U2370-1	2964
23859	7590	05/24/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C.			PESELEV, ELLI	
SUITE 1000			ART UNIT	
999 PEACHTREE STREET			PAPER NUMBER	
ATLANTA, GA 30309-3915			1623	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,463	Applicant(s) ROBERTS ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,9-13 and 20 is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "toxicity of a substance" is not disclosed or suggested by the specification as originally filed.

Applicant's arguments filed April 9, 2004 have been considered but have not been found persuasive.

Applicant contends that the phrase "toxicity of a substance" is synonymous with "toxic insult" and that the specification is replete with examples of toxic substances. This argument has not been found persuasive. The specification fails to provide any definition of the phrase "toxicity of a substance". Note that the term "substance" encompasses all substances, including poisons. Pages 2, 4, 6 and 14 of the specification relate to the background of the invention. It is not clear from the specification that the term "substance" is limited to those substances set forth in the specification.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, for the reasons stated in the Office Action of December 5, 2003.

Applicant's arguments filed April 9, 2004 have been considered but have not been found persuasive.

The El-Bayoumy et al article has been noted but has not been found persuasive since it relates to organoselenium compounds which are structurally significantly

different from the claimed compounds. Further, claims 16-19 are not limited to the administration of the effective amount of the active compound.

Applicant contends that the administration of thio- compounds and selenium to treat those conditions recited in claims 17 and 19 was well known in the art prior to the claimed invention. This argument has not been found persuasive. For example, Bayoumy et al article (Journal of Cellular Biochemistry, Supplement 22:92-100 (1995)) disclose the compound p-XSC decreased lung tumor multiplicity from 7.6 tumors per mouse to 4.1, 3.3 and 1.8 tumors per mouse i.e. the article clearly shows that the tested compounds was not effective in preventing the formation of tumors but in reducing the number of tumors. Further, the cancer tested in the article was caused by chemical carcinogens. The instant claims encompass prevention of any type of cancers, including those that are not caused by carcinogens. Note that the term "preventing" encompasses treating healthy host and preventing the same from ever getting a disease i.e. it reads on vaccine. Applicant has not provided any evidence that the claimed methods are effective as vaccines. Further, applicant has not provided any evidence that the claimed methods are effective in improving cardiovascular function or slowing the aging process. Note that the terminology "improving cardiovascular function" encompasses treating heart attack patients. There is no evidence of record or in the prior art that the selenium compounds are effective in treating heart attack patients or slowing the aging process. In view of the high unpredictability of the treatment and prevention of the conditions encompassed by the instant claims and the

lack of any evidence showing the activity of the claimed compounds, there is good reason to doubt the effectiveness of the claimed methods.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200